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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,229

Applicant(s)

SCHEINER ET AL.

Examiner

Kristen L Droesch

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22,56-65 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59-65,76 and 77 is/are allowed.
- 6) ☒ Claim(s) 1-22,56-58 and 73-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to provide support for the plurality of heart sound sensors being located within the implantable device. The specification on Page 7, lines 22-29 fails to state that the plurality of are located within the housing. The specification on Page 7, lines 12-21 only provides support for a single accelerometer being located within an implantable device.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1 recites the limitation "the sensor" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 3762

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 9-11, 13-16, and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson et al. (5,792,195).

Regarding claims 9, and 20, Carlson et al. shows a first heart sound sensor, (34) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (26), an interface circuit (42) and a control circuit (32, 36, 38) that includes a bandpass filter (46), a systole detector, and an ensemble averager (96, 98) (Fig. 2; Col. 6, lines 44 -55; Col. 7, lines 23-58).

Regarding claims 10-11, and 21, Carlson et al. further shows the heart sound sensor is an accelerometer (34) located internal to the implantable housing (10)

With respect to claim 19, Carlson et al. shows the data transmitted is processed data (Col. 4, lines 46-62).

Regarding claim 13, the second sensor includes an EGM sensing electrode (16,18,20,22) and the second signals are representative of EGM electrical signals.

Art Unit: 3762

With respect to claims 14-16, and 22, Carlson et al. shows the second sensor (24) includes an atrial sensing electrode (20, 22), and the third sensor (26) includes a ventricular sense electrode (16, 18) wherein the second sensor is disposed in the right side of the heart.

Regarding claim 20, Carlson et al. shows a systole detector where detection of systole triggers the ensemble averager (Col. 6, line 40 –Col. 7, line 13).

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4, 8, and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Lekholm (4,763,646). Carlson et al. shows a first heart sound sensor, an interface circuit (42) and a control circuit (32, 36, 38) that includes an ensemble averager (96, 98) (Fig. 2; Col. 6, lines 44 -55; Col. 7, lines 23-58). Although Carlson et al. fails to show the heart sound sensor includes a plurality of sensors, attention is directed to Lekholm which teaches an implantable device with a plurality of heart sound sensors (22, 23, 24). Lekholm teaches that the plurality of sensors can be placed to measure the atrium, or the ventricle, or placed where it can measure both the atrium and ventricle depending on the

Art Unit: 3762

application and function of the system (Col. 3, line 64-Col. 4, line 9). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Carlson et al. with a plurality of sound sensors as Lekholm teaches in order to place sensors to measure the atrium, or ventricle, or where the sensor can measure both the atrium and ventricle depending on the application and function of the system.

Regarding claims 2, Lekholm shows the plurality of heart sound sensors includes an accelerometer (Col. 1, lines 32-34).

With respect to claim 4, Lekholm shows the plurality of heart sound sensors is located external to the implantable housing (Fig. 3).

With respect to claim 8, Carlson et al. shows the data transmitted is processed data (Col. 4, lines 46-62).

Regarding claim 73, Carlson et al. shows a systole detector where detection of systole triggers the ensemble averager (Col. 6, line 40 –Col. 7, line 13).

With respect to claim 74, Carlson et al. shows a bandpass filter (46) coupled to the sensor (34, 44) and ensemble averager (96, 98) where the output of the band pass filter is applied to the ensemble averager (Figs. 3A-3C).

Regarding claim 75, Carlson et al. shows the control circuit (32, 36, 38) comprises a band pass filter (46) a rectifier (78), coupled to the band pass filter and a low pass filter (80) coupled to the rectifier and the ensemble averager (96, 98) (Figs. 3A-3C).

9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Lekholm (4,763,646) as applied to claim 1, and further in view of Sholder et al. (5,899,928). Although Carlson et al. and Lekholm disclose the claimed invention except for

Art Unit: 3762

explicitly teaching the interface circuit is configured to communicate using radio frequency or optical signals, attention is directed to Sholder et al. who teaches it is well known to use RF and optical signals for communication between implantable devices and external devices. (Col. 8, lines 52-55). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the interface circuit as taught by Carlson et al. and Lekholm with an interface circuit that communicates via RF or optical signals, since applicant has not disclosed that these particular communication means provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any means for communication such as the RF or optical signal communication taught by Sholder et al. for communication between an implantable device and an external device.

10. Claim 7, is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Lekholm (4,763,646) as applied to claim 1, and further in view of Turcott (6,409,675). Although Carlson et al. and Lekholm disclose the claimed invention except for explicitly teaching the transmitted data includes raw data determined by digitizing the sensed signals, attention is directed to Turcott which shows raw data can be recorded by an implantable device and transmitted via telemetry to an external processor (Col. 14, lines 38-48). It would have been obvious to one with ordinary skill in the art at the time the invention was made to transmit raw data rather than processed data because it would be far simpler and the step of processing the data would be omitted. Omission of an element and its function if the function of the element is not desired is generally recognized as being within the level of ordinary skill in the art. In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

Art Unit: 3762

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Lekholm (4,763,646). Although Carlson et al. discloses the claimed invention except for the heart sound sensor being located externally from the implantable housing, attention is directed to Lekholm who teaches that the heart sound detector can be located on a separate line or on an electrode lead. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the sensor as taught by Carlson et al. with the sensor of Lekholm, since applicant has not disclosed that this location of the sensor provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the sensor such as the external location taught by Lekholm for detecting heart sounds.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Tockman et al. (5,540,727). Although Carlson et al. discloses the claimed invention except for explicitly teaching the second sensor is located in a left side of a heart, attention is directed to Tockman who shows a similar device with a sensor (27, 29) located in the left side of the heart for sensing ventricular electrical signals (Col. 3, lines 20-28). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to locate the second sensor in a left side of a heart, since applicant has not disclosed that this particular location provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the second sensor such as the location in a left heart taught by Tockman et al. for sensing left ventricular electrical signals.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Turcott (6,409,675). Although Carlson et al. discloses the claimed invention except for

Art Unit: 3762

explicitly teaching the transmitted data includes raw data determined by digitizing the sensed signals, attention is directed to Turcott which shows raw data can be recorded by an implantable device and transmitted via telemetry to an external processor (Col. 14, lines 38-48). It would have been obvious to one with ordinary skill in the art at the time the invention was made to transmit raw data rather than processed data because it would be far simpler and the step of processing the data would be omitted. Omission of an element and its function if the function of the element is not desired is generally recognized as being within the level of ordinary skill in the art. In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

14. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of in view of Lekholm (4,763,646) and Tockman et al. (5,540,727).

With respect to claim 56, Turcott shows a method of outputting heart sounds using an implanted system including receiving first data representative of detected heart sounds (Col. 7, lines 37-40), applying control signals to an output device to cause the output device to generate outputs representative of the detected heart sounds (Col. 13, lines 60-65).

Although Turcott fails to show detecting heart sounds using a plurality of implanted heart sound sensors, attention is directed to Lekholm which teaches an implantable device with a plurality of heart sound sensors (22, 23, 24). Lekholm teaches that the plurality of sensors can be placed to measure the atrium, or the ventricle, or placed where it can measure both the atrium and ventricle depending on the application and function of the system (Col. 3, line 64-Col. 4, line 9). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott with the method of using a plurality of sound sensors as Lekholm teaches in order to place sensors to measure the atrium, the ventricle,

Art Unit: 3762

or where the sensor can measure both the atrium and ventricle depending on the application and function of the system.

Although Turcott fails to show generating data representative of heart sounds using ensemble averaging, attention is directed to Tockman et al., which teaches generating data representative of heart sounds using ensemble averaging in order to eliminate transient non-periodic noise (Col. 3, line 66-Col. 4, line 4, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott. with generating data representative of heart sounds using ensemble averaging as Tockman et al. teaches in order to eliminate transient non-periodic noise.

15. Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of in view of Lekholm (4,763,646) and Tockman et al. (5,540,727) as applied to claim 56, and further in view of Little et al. (4,628,939). Turcott further shows detecting first and second cardiac electrical signals using a second and third implanted sensor and transmitting data representative of the first and second cardiac electrical signals to the external system (Col. 15, lines 35-49). Although Turcott, Lekholm, and Tockman fail to show simultaneously displaying the data representative of the heart sounds and the data representative of the first and second cardiac electrical signals, attention is directed to Little et al. which shows displaying an electrocardiogram signal and phonocardiogram signal simultaneously in order to circumvent the inherent subjective difficulty in interpretation of heart sounds (Col. 2, line 64-Col. 3, line 2). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott, Lekholm, and Tockman with simultaneously displaying an electrocardiogram signal and phonocardiogram signal as Little et

Art Unit: 3762

al. teaches in order to circumvent the inherent subjective difficulty in interpretation of heart sounds.

Response to Arguments

16. Applicant's arguments with respect to claims 1-8, 56-58, and 73-75 have been considered but are moot in view of the new ground(s) of rejection.

17. Applicant's arguments filed 4/3/03 with respect to claims 9-22 have been fully considered but they are not persuasive. The additions made to claims 9 and 20 are deemed to be statements of intended use which have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Allowable Subject Matter

18. Claims 59-65, and 76-77 are allowed. The prior art of record fails to teach or suggest a method including generating first data representative of heart sounds *in the implanted system*, receiving the data *from the implanted system*, generating control signals using the first data in combination with generating timing comparison control signals and applying the control signals and the timing comparison control signals to an output device to generate representations of heart sounds and timing information.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Heinze et al. (5,247,945) shows an electrode with a plurality of heart sound sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Drael

kld

Kennedy Schaetzle
KENNEDY SCHAETZLE
PRIMARY EXAMINER
10-24-03